

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:

HOWARD STARK PROFESSIONAL
PHARMACY, INC.
d/b/a HOWARD STARK
PROFESSIONAL PHARMACY
6675 Holmes
Kansas City, MO 64131
Permit No. 002551

Complaint No. 2016-003134

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF
PHARMACY AND HOWARD STARK PROFESSIONAL PHARMACY,
INC. d/b/a HOWARD STARK PROFESSIONAL PHARMACY**

COME NOW Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Professional Pharmacy ("Respondent" or "Howard Stark Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement ("Settlement Agreement") for the purpose of resolving the question of whether Respondent's permit to operate as a pharmacy will be subject to discipline. For purposes of the terms included herein, including the disciplinary period, as defined below, the effective date of this Settlement Agreement is July 5, 2019 (the "Effective Date").

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri ("Administrative Hearing Commission") and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by

competent and substantial evidence; the right to cross-examine any witness appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the complaint (the "Complaint") filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For purposes of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit as a pharmacy, numbered 002551, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy (the "Board") is an agency of the State of Missouri created and established pursuant to §338.110, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Respondent Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Professional Pharmacy, 6675 Holmes, Kansas City, Missouri, was permitted by the Board under permit number 002551. Respondent's permit was at all times relevant herein current and active.

¹ All statutory references are to the Revised Statutes of Missouri 2016, as amended, unless otherwise stated.

3. Howard Stark Professional Pharmacy, Inc. d/b/a Stark Pharmacy is located at 5701 W 119th Street, Overland Park, Kansas ("Stark Pharmacy").

4. At all relevant times herein, the owners of Howard Stark Pharmacy and Stark Pharmacy were Steven D. Baraban, Steven John Schafer and Gary Gray, each with a one-third ownership interest in both pharmacies.

5. At all relevant times herein, Steven D. Baraban ("Baraban") was the Pharmacist-in-Charge ("PIC") of Howard Stark Pharmacy.

6. At all relevant times herein, Steven John Schafer was the PIC of Stark Pharmacy.

7. From 2013 until December, 2015, Howard Stark Pharmacy ordered and purchased drug ingredients used in pain cream compound preparations it dispensed to Missouri patients.

8. The drug ingredients used in the pain creams were shipped directly to Howard Stark Pharmacy from the suppliers.

9. Howard Stark Pharmacy shipped or delivered the drug ingredients used in the pain creams to Stark Pharmacy.

10. The drug ingredients Howard Stark Pharmacy ordered, purchased, transferred and distributed to Stark Pharmacy included tramadol, ketamine, ketoprofen, baclofen, diclofenac, cyclobenzaprine, versapro cream, lidocaine hcl, lidocaine base, gabapentin, nifedipine, flurbiprofen, prilocaine, bupivacaine, imipramine, lamotrigine 100mg, meloxicam 15mg, and lidocaine/prilocaine cream 2.5/2.5%.

11. Stark Pharmacy used the drug ingredients it received from Howard Stark Pharmacy to make batch compound pain creams, which were ultimately dispensed to patients by Howard Stark Pharmacy.

12. Pursuant to the practice of anticipatory compounding, Respondent contacted Stark Pharmacy by telephone and told Stark Pharmacy which medications Howard Stark Pharmacy needed to be compounded.

13. A dedicated staff member of Stark Pharmacy personally drove batches of compounded pain cream preparations to Howard Stark Pharmacy.

14. These compounded pain creams were driven from Stark Pharmacy to Howard Stark Pharmacy in 60 or 120-gram bottles. Each individual compound was labeled with the Formula ID number and lot number of the medication.

15. Howard Stark Pharmacy then added a patient-specific label generated from its computer system to the bottles when it dispensed the prescriptions to its patients.

16. Stark Pharmacy created batch compound log records for the batch compounds it prepared for Howard Stark Pharmacy.

17. Howard Stark Pharmacy and Stark Pharmacy did not share a computer system.

18. Neither Howard Stark Pharmacy nor Stark Pharmacy had a Missouri Class J pharmacy permit.

19. Howard Stark Pharmacy created a patient-specific compound log for each prescription dispensed from Howard Stark Pharmacy from a batch compound prepared at and by Stark Pharmacy and delivered to Howard Stark Pharmacy.

20. A substantial number of the lot numbers, dispensing dates, ingredients, beyond use dates and/or verifying pharmacist identified in Howard Stark Pharmacy's compounding records were inaccurate.

21. Respondent did not take an inventory of hydrocodone products once hydrocodone became a Schedule II controlled substance on October 6, 2014.

22. Respondent delegated the inventory responsibilities to Baraban as PIC.

Failure to obtain and comply with Class J permit requirements

23. A Class J Shared Service pharmacy permit is defined in 20 CSR § 2220-2.020(9)

as follows:

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

24. Missouri law defines the circumstances under which a pharmacy may share services with another pharmacy, which includes each pharmacy location obtaining a Class J permit, to-wit:

(I) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(B) There must be record keeping systems between shared service pharmacies with real time on-line access to shared services by both pharmacies. . . .

(C) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review upon request and that includes, but is not limited to, the

following:

1. A description of how the parties will comply with federal and state laws and regulations;
2. The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
3. The maintenance of a mechanism for tracking the prescription drug order during each step in the process;
4. The provision of adequate security to protect the confidentiality and integrity of patient information;
5. The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems.

20 CSR § 2220-2.650(1).

25. Howard Stark Pharmacy violated 20 CSR § 2220-2.650(1)(A) by failing to maintain a Class J permit and by sharing services with Stark Pharmacy which also did not have a Class J permit.

26. Howard Stark Pharmacy violated 20 CSR § 2220-2.650(1)(C) by failing to maintain a policy and procedures manual relating to its shared prescription processing services.

27. By operating as a Class J pharmacy without a valid Class J pharmacy permit, Howard Stark Pharmacy also violated § 338.220.1(10), RSMo, which prohibits the opening, establishment, operation, or maintenance of a pharmacy without first obtaining a proper permit from the Board, to-wit:

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. The following classes of pharmacy permits or licenses are hereby established:

* * *

(10) Class J: Shared service.

28. Respondent violated 19 CSR § 30-1.042(3) by failing to take its 2014 controlled substance inventory within one year from the prior year's inventory and by taking the 2013

Schedule II controlled substance inventory on a date different from the Schedules III through V controlled substance inventory.

CONCLUSIONS OF LAW

29. Based on the foregoing, cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under §338.055.2(5), (6), (12), (13), (15), RSMo, which states, in pertinent parts:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against anyholder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence.

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045, RSMo:

1. Respondent's pharmacy permit number 002551 shall be **SURRENDERED**, effective upon execution of the attached Affidavit of Voluntary Surrender of Pharmacy Permit.
2. Respondent shall sign the attached Affidavit of Voluntary Surrender of Pharmacy Permit and the terms and conditions set forth in the attached Affidavit of Voluntary Surrender of Pharmacy Permit shall apply and herein bind Respondent and all of its corporate members and representatives, if any.
3. Respondent agrees not to submit an Application to the Board for a period of five (5) years from the date of the Settlement Agreement herein executed.
4. No other corporate representative of Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Professional Pharmacy, if any, shall be allowed to submit an Application for New Pharmacy Permit for a period of five (5) years from the date of the Settlement Agreement herein executed.
5. Respondent shall return all indicia of licensure, i.e., the computer generated 5" x 7" license, and the wallet card, to the Board Office on or before the effective date of this agreement.
6. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

7. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for Respondent to be heard before the Board, or Administrative Hearing Commission if such a hearing is required by law, in accordance with the provisions of Chapter 536, RSMo.

8. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

9. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

10. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 338, 610 and 324, RSMo.

**RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE
LINE,**

 REQUESTS

 X **DOES NOT REQUEST**

**THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS
SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT
TO OPERATE AS A PHARMACY.**

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

HOWARD STARK
PROFESSIONAL PHARMACY,
INC. d/b/a/ HOWARD STARK
PROFESSIONAL PHARMACY

By: 

As Authorized Agent for HOWARD
STARK PROFESSIONAL
PHARMACY, INC. d/b/a/ HOWARD
STARK PROFESSIONAL
PHARMACY

Printed: Stephen J Schafar

Date: 6-6-19

PETITIONER

MISSOURI BOARD
OF PHARMACY

By: 

Kimberly Grinston
Executive Director

Date: 6-20-19

NEWMAN, COMLEY & RUTH P.C.

By: 

Alicia Embley Turner #48675
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: (573) 634-2266
Fax: (573) 636-3306
turnera@ncrpc.com

Attorneys for Missouri Board of
Pharmacy

AFFIDAVIT OF VOLUNTARY SURRENDER
OF PHARMACY PERMIT

STATE OF Kansas)
) ss
COUNTY OF Johanson)

I, STEVEN T SCHAFER, being first duly sworn upon my oath state:

1. I am the Vice President of Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Pharmacy, 6675 Holmes, Kansas City, Missouri 65131, a pharmacy licensed by the Missouri Board of Pharmacy ("Missouri Board of Pharmacy" or the "Board") as permit number 002551.
2. I understand that the Missouri Board of Pharmacy is authorized to pursue disciplinary action upon permit number 002551, and that the Missouri Board of Pharmacy is not required to accept a voluntary surrender of this permit.
3. It is the pharmacy's intent and desire at this time, after due deliberation, to voluntarily surrender its pharmacy permit, number 002551, to the Missouri Board of Pharmacy and to provide that Board with any other documents or certificates in its possession evidencing the existence of said Missouri pharmacy permit.
4. I further understand and agree that if Howard Stark Pharmacy, Inc. d/b/a Howard Stark Pharmacy, applies for licensure in the State of Missouri following the execution of this Affidavit, all facts and information, if any, gathered prior to execution of this affidavit by the Missouri Board of Pharmacy concerning any possible or alleged violations of Chapter 338, RSMo, may be considered in the Board's decision of whether to grant a new pharmacy permit.
5. I fully understand that, by my execution of this Affidavit, Howard Stark Pharmacy, Inc. d/b/a Howard Stark Pharmacy, shall surrender and lose any rights under the law to operate as a pharmacy in the State of Missouri and will not be able to again operate as a pharmacy until a new Missouri pharmacy permit application is submitted to and approved by the Board.

6. I further understand that the abovementioned pharmacy permit will not be returned by the Missouri Board of Pharmacy and that such permit will cease to exist when it is surrendered.

7. I acknowledge and affirm by this sworn statement that no threats, promises, or assurances of any kind have been made regarding the voluntary surrender of the permit except as noted above, nor have I been threatened or coerced to so act in any way, but rather Howard Stark Professional Pharmacy, Inc. d/b/a Howard Stark Pharmacy does hereby voluntarily surrender its Missouri pharmacy permit by and with this Affidavit.

8. I acknowledge and affirm that I understand that the Board of Pharmacy will maintain this Affidavit of Voluntary Surrender as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

HOWARD STARK PROFESSIONAL
PHARMACY, INC. D/B/A HOWARD STARK
PHARMACY

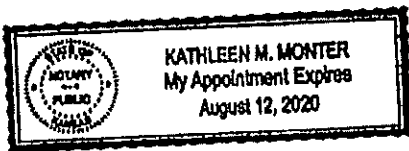
Date: 6-6-19

By: _____

Stephen T. Schaefer
(printed)

Title: Vice President

Subscribed and sworn to before me this 6th day of June, 2019.



Kathleen M. Monter
Notary Public

My Commission Expires: August 12, 2020

Kathleen M. Monter
(Print, type or stamp name of notary)